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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,262	09/12/2003	John Coogan	98103.00017	7783

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EXAMINER	
HANLEY, SUSAN MARIE	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,262	COOGAN ET AL.	
	Examiner	Art Unit	
	Susan Hanley	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/11/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 are presented for examination.

Claims Suggestion

In claim 12, it is suggested that the phrase "wavelength below 340 nm" be changed to "wavelength less than 340 nm".

Claim Rejections - 35 USC § 112

Claims 7, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is rejected because it is unclear what is having its one or more nucleic acids disrupted.

Claim 9 is rejected because the photoactive agent lacks antecedent basis in claim 1. Claim 1 does not recite a photoactive agent in the complex fluid. Furthermore, the phrase "specific chemical adduct" is vague and indefinite. The nature of the adduct and the specificity of the adduct to the photoactive agent is undefined.

Claim 10 is rejected because it is unclear what the "desired chemical compound " is and from what it originates. Is a precursor of the desired chemical compound added to the complex fluid or does the desired chemical compound originate from some part of the complex fluid? Also, the phrase "involves chemical synthesis" is vague and indefinite. It is unclear what entity is responsible for the synthesis. Is it the energy from the excimer light source or some part of the complex fluid?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12-19 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Hlavinka (US 2002/0015662).

Hlavinka discloses a method for the inactivation of pathogens in fluids wherein the fluid is blood or a blood product that contains proteins. The method comprises mixing a non-toxic amount of a photosensitizer to a fluid and exposing the mixture to a pulsed radiation source to activate the photosensitizer whereby the pathogens are inactivated (abstract). The photosensitizer can be endogenous, such as riboflavin (p. 1, last 10 lines of section [0005], as in claims 12 and 17. The photosensitizer absorbs radiation and transfers the absorbed energy to an energy acceptor (section [0004]. The excited photosensitizer can react with DNA or RNA , as in claim 10. The photoradiation source can deliver light in a wavelength range between 280-550 nm. This range overlaps part of the claimed range of less than 340 nm, as in instant claim 12. . UV light having a wavelength less than 320 nm that is delivered to the fluid will inherently inactivate nucleic acid and proteins. The light source is one that can be pulsed and includes those generated by intense flashed of an inert gas such as xenon (section [0046]). The pulsed light can be mono- or polychromatic (sections [0021] and [0054]). A single light source can provide a mixture of light at varying wavelengths (section [0056]). Microorganisms that can be eradicated by the methods include virus such as HIV (which is an RNA-based virus, thus meeting the limitation of instant claim 18) or microorganism such as *S. aureus* which has DNA, as in instant claim 19.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 5, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prodouz et al. (1987; "Prodouz") in view of Whitehurst (US5,843,143), Kogelschatz et al. (2000; "Kogelschatz") and Oppenlander (1998).

Prodouz discloses that UV laser radiation inactivates viruses in fluids comprising platelets and plasma. The radiation was generated by a XeCl excimer laser that delivered pulses of UV light at 308 nm. Low intensity doses of the laser light inactivated the virus. However, high does exposure significantly inactivated platelets and plasma. Prodouz concludes that the method at high intensity could be improved by the use of photoactivating agents as well as modification of radiation wavelength and pulse rate (p. 591, last paragraph). Thus, Prodouz meets, in part, the limitations of claims 1 and 7 because monochromatic excimer-based light having a wavelength between 260 and 310 nm what used to selectively activate the DNA or a virus contained in a fluid having plasma or platelets. Platelets and plasma are blood products, as in claims 2 and 8. The disclosure of XeCl light meets instant claim 5.

Prodouz does not teach that the excimer-based light source is a nonlaser excimer-based radiation source.

Whitehurst discloses that lasers are well known for medical applications but they have a number of disadvantages including high cost, bulky power supplies and being overly sophisticated for the intended use. Whitehurst teaches that incoherent or non-laser light sources that have a light intensity lamp can provide monochromatic light for photodynamic therapy (col. 1, lines 8-25, 46-52; col. 2, lines 60-68).

Kogelschatz discloses high-intensity sources of incoherent UV and vacuum UV excimer radiation that provide narrow-band radiation at selected wavelengths depending upon the combination of gas/halide mixture which range from 157 to 354 nm (Table 1, p. 30). The disclosed excimer lamps have several advantages including their efficient energy conversion, monochromatic output, and ability to be pumped at light power densities (abstract). Kogelschatz discloses industrial uses for the incoherent excimer radiation sources.

Oppenlander disclose that incoherent excimer lamps are superior to mercury lamps for radiation output and teaches the use of said excimer lamps for photochemical treatment of water. Oppenlander reports that the excimer lamps were superior to the mercury lamps. Oppenlander reports that excimer lamps have improved radiation efficiency and that they have broad technical applications beyond water treatment technologies (p. 504-505, connecting paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute nonlaser, excimer-based lamps for a excimer laser in the virus inactivation method of Prodouz. The ordinary artisan would have been motivated to do so because Prodouz expressed a need to modify the delivery of radiation to blood components by the laser since the delivery of radiation by the laser inactivated platelets and plasma. The ordinary artisan would have been motivated to employ an incoherent non-laser light source such as an excimer-based lamp because they lack the shortcomings of the laser-based delivery and are capable of delivering high intensity monochromatic light to a target. The ordinary artisan would have had a reasonable expectation that the excimer-based system would work in the method of Prodouz because it delivers the desired monochromatic wavelength.

Claims 1-5, 7, 8 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prodouz et al. (1987; "Prodouz") in view of Whitehurst (US5,843,143), Kogelschatz et al. (2000; "Kogelschatz") and Oppenlander (1998), as applied to claims 1, 2, 5, 7 and 8, in further view of Hlavinka (US 2002/0015662).

The combined disclosures by Prodouz, Whitehurst, Kogelschatz and Oppenlander is discussed supra.

The combined disclosures do not teach the addition of a photoactive compound, a system for controlling the temperature or the mixing of the blood product to be decontaminated by the non-laser excimer-based light source.

The disclosure by Hlavinka is discussed supra. Briefly, Hlavinka teaches that it is advantageous to add photosensitizer to blood products for the inactivation of pathogens in fluids because the photosensitizer is able to focus its photodynamic affect on microorganisms and viruses with little or not effect upon accompanying cells or proteins (lines 10-15 of section [0005]). Hlavinka also teaches that it is desirable to mix the product to be irradiated to improve the efficiency of pathogen inactivation (section [0023]. Hlavinka also disclose the use of temperature sensors and other cooling mechanisms where necessary to keep the temperature below temperatures at which desired proteins and blood components in the fluid being irradiated are damage (section [00530].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a photosensitizer, control the temperature and mix a blood component fluid that is decontaminated by radiation from a nonlaser excimer light source. The ordinary artisan would have been motivated to employ a photosensitizer, control the temperature and mix a blood component fluid because all of these additional step improve the decontamination method as discussed by Hlavinka. The ordinary artisan would have had a reasonable expectation that the employment of a photosensitizer, controlling the temperature and mixing the blood component-containing fluid that is decontaminated by

radiation from a nonlaser excimer light source because Hlavinka demonstrated these additional methods are suitable for decontamination methods by radiation sources.

Claims 1, 2, 5, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prodouz et al. (1987; "Prodouz") in view of Whitehurst (US5,843,143), Kogelschatz et al. (2000; "Kogelschatz") and Oppenlander (1998), as applied to claims 1, 2, and 5-8, in further view of Miripol et al. (US 4,952,812 which is cited in the IDS filed 2/11/04; "Miripol") and de With et al. (1994; "de With").

The combined disclosures by Prodouz, Whitehurst, Kogelschatz and Oppenlander is discussed supra.

The combined disclosures do not teach leukocyte reduction wherein the first fluid component is a carrier fluid.

Miripol teaches that a thin film or layer of white blood cells such as the contaminating while cells in a platelet concentrate are irradiation with UC light having a wavelength between 280 to 320 nm.

de With discloses that laser light generated by and XeCl excimer at 308 nm can break DNA strands of leukocytes in phosphate-buffered saline (abstract and p. 47, right column, last paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a nonlaser excimer-based light source for the reduction of leukocytes in a carrier liquid. The ordinary artisan would have been motivated to do so because an excimer-based lamp because they lack the shortcomings of the laser-based delivery and are capable of delivering high intensity monochromatic light to a target. The ordinary artisan would have had a reasonable expectation that the excimer-based system would work in a leukocyte reduction method because it delivers the desired monochromatic wavelength.

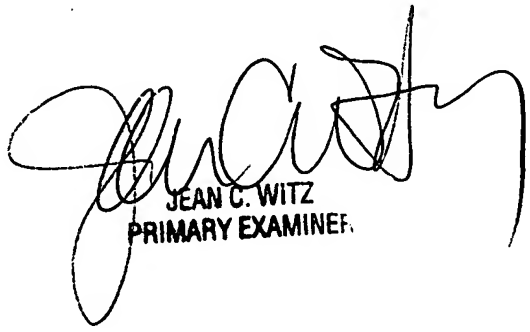
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Hanley
Patent Examiner
1651



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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